

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Macrogolglycerol Hydroxystearate 40
Castor oil, hardened, ethoxylated
- **Article number:** 700362, 101231
- **CAS Number:**
61788-85-0
- **NLP Number:**
500-147-5
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pharma excipient
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
FAGRON a.s.
Holická 1098/31m
779 00 Olomouc
Česká republika
- **Further information obtainable from:**
Tel.: +420 585 222 590
info@fagron.cz
- **1.4 Emergency telephone number:**
Toxikologické informační středisko,
Na Bojišti 1,
128 08 Praha 2
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),
e-mail:tis.cuni@cesnet.cz

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified, according to the CLP regulation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**
CAS: 61788-85-0 Macroglycerol Hydroxystearate 40
Castor oil, hardened, ethoxylated
- **Identification number(s)**
- **NLP Number: 500-147-5**

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
Water spray
Foam
Fire-extinguishing powder
Carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
Chloroprene rubber, CR
Nitrile rubber, NBR
Butyl rubber, BR
Recommended thickness of the material: $\geq 0,7$ mm
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection** Goggles recommended during refilling
- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid

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Safety data sheet

according to 1907/2006/EC, Article 31

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Revision: 11.07.2023

Version number 1.2 (replaces version 1.1)

Trade name: Macrogolglycerol Hydroxystearate 40
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· Colour:	Whitish
· Odour:	Odourless
· Odour threshold:	Not determined.
· Melting point/freezing point:	16–26°C
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	242°C
· Ignition temperature:	375°C
· Decomposition temperature:	Not determined.
· pH	6–7
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water at 23°C:	>490 g/l
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20°C:	1,026 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

· 9.2 Other information	
· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Auto-ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void

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Trade name: Macroglycerol Hydroxystearate 40
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· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Assessment by list): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

• 14.1 UN number or ID number • ADR, IMDG, IATA	not regulated
• 14.2 UN proper shipping name • ADR, IMDG, IATA	not regulated
• 14.3 Transport hazard class(es) • ADR, ADN, IMDG, IATA • Class	not regulated
• 14.4 Packing group • ADR, IMDG, IATA	not regulated
• 14.5 Environmental hazards:	Not applicable.
• 14.6 Special precautions for user	Not applicable.
• 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
• UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
Substance is not listed.

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- **REGULATION (EU) 2019/1148**
- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
Substance is not listed.
- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
- **Regulation (EC) No 273/2004 on drug precursors** Substance is not listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Fagron Česká republika
- **Contact:** msds@fagron.cz
- **Date of previous version:** 05.04.2022
- **Version number of previous version:** 1.1
- **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
- *** Data compared to the previous version altered.**

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